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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/608,166	06/27/2003	Alan J. Mautone	SDR-03DIV	8257

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EXAMINER	
JAGOE, DONNA A	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 03/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/608,166	MAUTONE, ALAN J.	
	Examiner	Art Unit	
	Donna Jagoe	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-64* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-64* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/8/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-64 are presented for examination.

Information Disclosure Statement

The listing of references in the Search Report is not considered to be an information disclosure statement (IDS) complying with 37 CFR 1.98. 37 CFR 1.98(a)(2) requires a legible copy of: (1) each foreign patent; (2) each publication or that portion which caused it to be listed; (3) for each cited pending U.S. application, the application specification including claims, and any drawing of the application, or that portion of the application which caused it to be listed including any claims directed to that portion, unless the cited pending U.S. application is stored in the Image File Wrapper system; and (4) all other information, or that portion which caused it to be listed. In addition, each IDS must include a list of all patents, publications, applications, or other information submitted for consideration by the Office (see 37 CFR 1.98(a)(1) and (b)), and MPEP § 609 subsection III. A(1) states, "the list ... must be submitted on a separate paper." Therefore, the references cited in the Search Report have not been considered. Applicant is advised that the date of submission of any item of information or any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the IDS, including all "statement" requirements of 37 CFR 1.97(e). See MPEP § 609 subsection III. C(1).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 43 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "performance enhancing medicament" in claim 1 is a relative term, which renders the claim indefinite. The term "performance enhancing" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is unclear to the examiner what is meant by performance enhancing medicament. Does it enhance the performance of the Eustachian tube lumen or does it enhance some other element that is not recited in the claim? Since no guidance is provided as to how "enhanced the performance of the unknown element a can be and still fall within the scope of the instantly claimed subject matter as circumscribed by the term "performance enhancing medicament" the metes and bounds of the term are not clear, making it impossible to ascertain with reasonable precision when that term is infringed and when it is not.

Clarification is required.

Claim 43 recites the limitation "said Eustachian tube and middle ear" in line 9 of the claim. There is insufficient antecedent basis for this limitation in the claim because

the Eustachian tube and middle ear have not yet been recited in the beginning of the claim.

Claim 43 recites the limitation "said lining of the lumen and middle ear" in line 10 of the claim. There is insufficient antecedent basis for this limitation in the claim because the linings of the lumen and middle ear have not yet been recited in the beginning of the claim. Examiner suggests that applicant follows the structure of claim 20 for proper claim format.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 1-19 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 55-77 of U.S. Patent No. 6,616,913 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other. The instant claims are drawn to a process of preparing a Eustachian tube lumen patency and performance enhancing medicament. The prior art

claims are drawn to a method of preparing a Eustachian tube lumen patency medicament. The instant and conflicting claims recite substantially the same subject matter, differing only in the description of the particular components claimed. For instance, conflicting claims 55-77 requires the particular lipid surfactants, spreading agents and propellants. It differs in that the instant claims include sterols, lipids and fatty acids in the group of spreading agents. Since, for example, sterols generally would be included in cholesteryl esters, it would have been obvious to anyone of ordinary skill in the art that the claims overlap in scope in this manner. One skilled in the art would have been motivated to have interpreted the claims as broadly as is reasonable, and in doing so recognize that they are coextensive in scope and thus the proper subject of an obviousness-type double patenting rejection as outlined by *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970). The selection of particular lipids, fatty acids and sterols, are all conventional in the lipid surfactant art and would have been obvious with the broad recitation of lipid surfactant.

2. Claims 20-64 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 78-108 of U.S. Patent No. 6,616,913. Although the conflicting claims are not identical, they are not patentably distinct from each other. The instant claims are drawn to a process for preparing an otitis media medicament. The prior art claims are drawn to a process for preparing an otitis media medicament. The instant and conflicting claims recite substantially the same subject matter, differing only in the description of the particular

components claimed. For instance, conflicting claim 78-108 requires the particular spreading agents and instant claims 43-64 do not recite spreading agents. However, it is noted that there is overlap in the agents recited as spreading agents that the agents recited as lipid surfactants. It would have been obvious to anyone of ordinary skill in the art that the claims overlapped in scope in this manner. One skilled in the art would have been motivated to have interpreted the claims as broadly as is reasonable, and in doing so recognize that they are coextensive in scope and thus the proper subject of an obviousness-type double patenting rejection as outlined by *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

3. Claims 1-64 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 45-86 and 111-133 of U.S. Patent No. 6645467 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because generally the process for preparing the Eustachian tube lumen patency medicament and the process of preparing the otitis media medicament of the instant claims appears to substantially overlap with the process for preparing an upper respiratory airway enhancing medicament. The same components and limitations apply to both processes differing only in the intended use of the process. It would have been obvious to prepare medicaments to enhance Eustachian tube lumen patency motivated by the process of the prior art wherein an upper airway enhancing medicament is prepared with the same components in the same manner.

4. Claims 1-64 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 43-84 and 108-130 of copending Application No. 2002/0076383 (10/011626). Although the conflicting claims are not identical, they are not patentably distinct from each other because generally the process for preparing the Eustachian tube lumen patency medicament and the process of preparing the otitis media medicament of the instant claims appears to substantially overlap with the process for preparing an external auditory canal patency enhancing and protective medicament of the prior art. The same components and limitations apply to both processes differing only in the intended use of the process. It would have been obvious to prepare medicaments to enhance Eustachian tube lumen patency motivated by the process of the prior art wherein an external auditory canal patency enhancing medicament is prepared with the same components in the same manner.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

5. Claims 1-64 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 49-102 of U.S. Patent No. 6521213. Although the conflicting claims are not identical, they are not patentably distinct from each other because generally the process for preparing the Eustachian tube lumen patency medicament and the process of preparing the otitis media

medicament of the instant claims appears to substantially overlap with the process for preparing an otitis externa medicament of the prior art. The same components and limitations apply to both processes differing only in the intended use of the process. It would have been obvious to prepare medicaments to enhance Eustachian tube lumen patency motivated by the process of the prior art wherein an otitis externa medicament is prepared with the same components in the same manner.

6. Claims 20-64 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 5,306,483. Although the conflicting claims are not identical, they are not patentably distinct from each other because generally the process for preparing the Eustachian tube lumen patency medicament and the process of preparing the otitis media medicament of the instant claims appears to substantially overlap with the process for preparing lipid crystals in combination with a therapeutically active agent of the prior art. The same components and limitations apply to both processes differing only in the intended use of the process. It would have been obvious to prepare medicaments to enhance Eustachian tube lumen patency motivated by the process of the prior art wherein lipid crystals in combination with a therapeutically active agent is prepared with the substantially the same components in the same manner.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna Jagoe whose telephone number is (571) 272-0576. The examiner can normally be reached on Monday through Thursday from 9:00 A.M. - 3:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Art Unit 1614

03/18/2005

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